

REMARKS

Claims 1-13 are pending in the application and stand rejected. The claims have not been amended. For the examiner's convenience a full set of claims is attached at Tab A.

Applicant appreciates the examiner's thoughtful consideration of the remarks in the amendment dated September 1, 2004.

In the Office action claims 1-13 stand rejected for obviousness over *Aneas* WO 98/13006 in view of *Hiblar* or *Parker*. Of the rejected claims only claims 1, 12 and 13 are independent.

The Office action took the position that *Aneas* discloses a base adapted to be mounted on a recipient (3) and comprising a sleeve (12) with an inner bore (12a) and further discloses a hollow needle (5), a plunger (15), adapted to slide in the bore and has an edge of sleeve opposite a stopper (3b) provided with stop means (18) adapted to cooperate with complimentary means (16) provided on the plunger (15) to lock it in position of transfer. However, the Office action noted that *Aneas* does not disclose a needle with a non-circular cross section or a sleeve with a non-circular cross-section, such that the needle can slide in the sleeve without the possibility of rotation. However, the Office action indicated that it would have been obvious to modify the needle of *Aneas* and incorporate a non-circular needle/sleeve device as taught by *Hiblar* in order to prevent the unwanted rotation of the needle, as required by each independent claim 1, 12 and 13 of the invention.

Applicants request that the rejection be reconsidered and withdrawn in view of the following remarks. As an initial matter, the Applicants submit that one of skill in the art would not combine needles and sleeves in the catheter art with a needle and sleeve in the drug reconstitution art because of the significant differences in the operational demands upon the respective needles and devices caused by the different environments in which they operate. The needles used in the reconstitution art are for piercing relatively stiff rubber stoppers and are relatively thick and rigid. They also contain a relatively large diameter passage through which fluid can pass without generating excessive back pressure. The relatively rigid needles of reconstitution devices are used to pierce directly through relatively stiff stoppers in drug vials in a relatively uncontrolled manner, as compared to catheter needles. In contrast, the selection of appropriate needles for use in catheters depends on a variety of different factors including the fact that the needle must be deformable and have characteristics that make them capable of traversing the circulation system before reaching their point of use. In fact, the *Hiblar* needle

must be deformed just to exit the catheter and carry out its function. See Figure 2. Applicants submit that *Aneas* and *Hiblar* are not properly combinable because one of skill in the art would not look to the catheter arts in order to obtain suitable needle and sleeve configurations for reconstitution devices.

The references are not properly combinable for another reason. The *Aneas* needle already slides within its sleeve without the possibility of rotation within the sleeve. (See page 7, line 22 through page 8, line 7; which corresponds to Col. 4, lines 28-47 of corresponding US application 6,070,623) The *Aneas* plunger to which the needle is attached is blocked in rotation with respect to the skirt 12 by including grooves in the inner surface of the skirt that are parallel to the axis of the device and corresponding ribs on the plunger such that the plunger ribs engage the skirt grooves. Because rotation of the needle in the skirt is already prevented in *Aneas*, there would be no apparent advantage to the combination of *Aneas* with *Hiblar* which has a needle with a non-circular cross-section and sleeve having a non-circular inner cross-section for preventing the possibility of rotation of the needle with the sleeve.

Applicants submit that at least for these reasons Claims 1, 12 and 13 are allowable over *Aneas* in view of *Hiblar* and request that this rejection be withdrawn.

Claims 1, 12 and 13 also stand rejected as obvious over *Aneas* in view of *Parker et al.*

The Office action also took the position that it would have been obvious to combine *Aneas* with the *Parker* non-circular needle hub (4) with a non-circular sleeve (1.2) in order to prevent axial rotation of the needle relative to the sleeve. The Office action recognized that *Parker* fails to disclose a non-circular needle, as in the claimed invention, but maintained that one of skill would still realize that making the non-circular needle would have an advantage so as to make the present invention obvious.

Applicant respectfully requests that this rejection be reconsidered and withdraw because the cited references are not properly combinable and, even if combined, as acknowledged in the Office action, would not contain each of the limitations of the claimed invention. Namely, the suggested combination still would lack a needle having a non-circular cross-section and there is no suggestion in the references nor has the Office action pointed to any knowledge in the art that would motivate one having skill to add a noncircular needle to the combination so as to render the invention of Claims 1, 12 and 13 obvious. Conventional needles had and still do have

circular cross-sections and one of skill in the art would undoubtedly have selected such a needle for use in such a reconstitution device.

In addition, Applicant submits that *Aneas* and *Parker* are not properly combinable because *Aneas* already discloses a needle that slides within its sleeve without the possibility of rotation within its sleeve. Thus, there would be no reason to incorporate the *Parker* non-circular needle hub (4) and non-circular sleeve (1.2) in order to prevent axial rotation of the needle relative to the sleeve in the *Aneas* device to prevent rotation of the *Aneas* needle within its sleeve. There simply would be no advantage to such a combination nor do the references contain anything to suggest or motivate one of skill to make the combination.

Applicants submit that at least for these reasons Claims 1, 12 and 13 are allowable over *Aneas* in view of *Parker* and request that this rejection be reconsidered and withdrawn.

To establish a *prima facie* case of obviousness there must be some suggestion or motivation, either in the reference or references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In addition, all of the claim limitations must be taught or suggested by the prior art. A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach all aspects of the claimed invention is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. See M.P.E.P. 2143.01. Applicants respectfully submit that in the present case, a *prima facie* case of obviousness has not been established because no objective reason for combining the teachings of the references in such a manner as to obtain the present invention has been provided nor is such a reason apparent.

For these reasons Applicants submit that independent Claims 1, 12, and 13 are allowable and request that the rejections be withdrawn. In addition, Claims 2-11 which depend from Claim 1 are allowable at least for the same reasons as Claim 1.

In light of the foregoing comments, the Applicants respectfully submit that the application is in condition for allowance and request that a Notice of Allowance be issued in this case.

Respectfully submitted,

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